Response to Restriction Requirement and Amendment

Serial No.: 10/622,675 Filing Date: July 17, 2003

Title: Method for the Prediction of an Epitope

REMARKS/ARGUMENTS

I. THE CLAIM AMENDMENTS

Applicants have amended claims 4-6 and 15-20 to remove dependency upon non-elected claims. Accordingly, no new matter has been introduced by way of these amendments.

II. RESPONSE TO RESTRICTION

In response to the restriction requirement set forth in the Office Action mailed December 12, 2005, Applicants hereby elect Group I (claims 1, 4-10 and 15-20), with traverse. This election of claims is made without prejudice to Applicants' right to pursue the non-elected claims in one or more divisional applications in due course.

The Examiner classified the claims into four groups. According to the Examiner, Group I, consisting of claims 1, 4-10 and 15-20, is "drawn to a method for predicting at least part of a binding site of a target protein, ..."; Group II, consisting of claims 2, 4-6 and 11-20, is "drawn to a method for predicting at least part of a binding site in a target protein, ..."; Group III, consisting of claims 3, 4-6 and 11-20, is "drawn to a method for predicting at least part of a binding site in a target protein, ..."; and Group IV, consisting of claims 21-23 is "drawn to a computer implemented method for predicting at least part of a binding site in a target protein, ...". Office Action of December 12, 2005, page 2.

To sustain a proper requirement for restriction, the Examiner must demonstrate that the independent and distinct inventions meet two criteria. First, the inventions must be independent or distinct as claimed, and second, there must be a serious burden on the Examiner. (Manual of Patent Examining Procedure (MPEP), 8th Ed., §803). The Examiner can demonstrate a "serious burden" by "appropriate explanation of separate classification, or separate status in the art, or a different field of search...." (MPEP, 8th Ed., §803). Applicants assert that the Examiner has not fulfilled either of these requirements, as the Examiner has demonstrated neither that the

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inventions are distinct or independent, nor that a serious burden exists. Accordingly, Applicants assert that restriction is improper.

In making the rejection, the Examiner states that "the different inventions are directed to methods that are both physically and functionally distinct, and the particulars of one Group are not required for another." *Office Action of December 12, 2005*, page 3. The Examiner continues and states that "Groups II and II involve steps and conditions not found in Groups I or IV," *Office Action of December 12, 2005*, page 3.

The Office Action itself, however, belies the requirement for restriction. Every group of Groups I-III that the Examiner has constructed, save for Group IV, falls into class 435, subclass 7.1. See, Office Action of December 12, 2005, page 2. Moreover, the Examiner has characterized each of Groups I-III with nearly identical language in that, according to the Examiner, Groups I-III are "drawn to a method for predicting at least part of a binding site [of/in] a target protein," Office Action of December 12, 2005, page 2. Accordingly, Applicants assert that the Examiner has not met his burden by demonstrating that the alleged inventions are distinct and independent.

Even if the inventions are independent or distinct, there must be a demonstration that there would be a *serious burden* on the Examiner if restriction is not required. (Manual of Patent Examining Procedure (MPEP), 8th Ed., §803). Indeed, "in order to establish reasons for insisting upon restriction, [the Examiner] must explain why there would be a serious burden ... if restriction is not required." (MPEP, 8th Ed., §808.02). Applicants assert that the Examiner has not provided such an explanation and thus, has not met his burden.

A "serious burden" on the Examiner can be shown "by appropriate explanation of separate classification, or separate status in the art, or a different field of search...." (MPEP, 8th Ed., §§803, 808.02). As pointed out above, however, the Examiner has classified Groups I-III into the same class and subclass, thus demonstrating that the searches would not impose a serious burden on the Examiner. And "[i]f the search and examination of the entire application can be

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made without serious burden, the examiner *must* examine on the merits, even though it includes claims to independent or distinct inventions." (MPEP, 8th Ed., §803) (emphasis added).

Furthermore, searching a method for predicting at least part of a binding site of a target protein (Groups I-III) would provide helpful information for the examination of Group IV. For example, searching Group I, II or III, would provide helpful information for searching and examining claims drawn to "a computer-implemented method for predicting at least part of a binding site in a target protein, …" *Office Action of December 12, 2005*, page 2.

In summary, the Examiner has not provided any evidence that the inventions are unrelated and are not capable of use together. Furthermore, the Examiner has not demonstrated that there would be a serious burden on the Examiner if restriction is not required. For at least the reasons indicated above, Applicants assert that restriction is improper and should be withdrawn. At a minimum, Applicants request that the Examiner rejoin Groups I-III. Applicants earnestly await receipt of the Office Action on the merits.

III. ELECTION OF SPECIES

The Examiner asserts that the "application contains claimed directed to the following patentably distinct genus of the claimed invention: 1) molecule 2) target protein 3) cross-reactive protein." *Office Action of December 12, 2005*, page 4.

Applicants assert that no such species election is required in that the alleged species are simply elements of the claims, rather then individual members of a genus. Indeed, the claims are directed towards a method of predicting at least part of a binding site in a *target protein*. The binding site in the target protein is characterized by its ability to be bound by a *molecule*, *e.g.*, an antibody. The methods for predicting this biding site in a target protein comprise comparing components of a plurality of cross-reactive proteins. Thus, all three alleged species are elements of the claims, rather than members of a genus. Proper examination of the claims can not be made without examining all elements of the claims. Thus, to examine one element of the claim (*i.e.*, the alleged species) without examining the other elements would not be proper.

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If any extensions of time are necessary to prevent abandonment of this application, beyond the Petition for Extension of Time submitted herewith, such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required, including fees for net addition of claims, are hereby authorized to be charged to account number 50-3120.

Should the Examiner believe that further discussion of any remaining issues would advance the prosecution, he or she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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